

REMARKS

Favorable reconsideration of this application in view of the remarks to follow and allowance of the claims of the present application is respectfully requested.

In the Advisory Action dated January 31, 2006, the Examiner maintains the rejection to Claims 1-3, 5-12, 14, 21 and 22 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the amendment to Claims 1 and 15, filed November 4, 2003, to include "R is a C3-C6 cycloalkyl group, which is optionally substituted with a straight or branched C1-C6 alkyl group" in formula (I), does not find support in the original disclosure.

Applicants respectfully disagree for the reasons discussed below.

The specification explicitly teaches that the preferred compounds of formula (I) are those where R is a C3-C6 cycloalkyl or an optionally substituted straight or branched C1-C4 alkyl group, a cycloalkyl or an aryl or arylalkyl group and the more preferred compounds are those where R is a C3-C6 cycloalkyl (see page 11, lines 9-17).

Particularly, Claim 8, as originally filed, recites that "the method of Claim 1, wherein R is C3-C6 cycloalkyl group optionally substituted with a straight or branched C1-C6 alkyl group." (emphasis added)

Therefore, applicants respectfully submit that the amendment to Claims 1 and 15, filed November 4, 2003, to include "R is a C3-C6 cycloalkyl group, which is optionally substituted with a straight or branched C1-C6 alkyl group" in formula (I), is fully supported by the original disclosure, i.e., the specification and the claims, as originally filed.

The Examiner also maintains the rejection to Claims 1-3 and 5-14 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

Specifically, the Examiner alleges that present Claim 1 still includes HIV and Alzheimer's disease. The Examiner also asserts that the claimed treatment of cancer is not supported in the specification in view of the unpredictability of cancer therapy and the lack of working examples or other guidance in the specification.

Applicants respectfully submit that the specification contains sufficient information regarding the subject matter of the claims as to enable one skilled in the art to make and use the claimed methods of treating cell proliferative disorders without undue experimentation.

The test of enablement is whether one skilled in the art could make and use the invention from the disclosures in the application coupled with information known in the art without undue experimentation. However, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled in the art and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1986).

The present invention teaches ureido-pyrazole derivatives of formula (I) showing cdk/cyclin kinase inhibitory activity and the use thereof in treating cell proliferative disorders associated with an altered cell-dependent kinase (cdk) activity. Inasmuch as compounds of formula (I) inhibit the activity of cdk/cyclin kinase, a cell proliferative disorder associated with an altered cdk activity may be treated with the claimed method of administering a compound of formula (I) to a mammal in need thereof. Thus, applicants believe the claimed method of administering a compound of formula (I) to a mammal in need thereof for the treatment of cell proliferative disorders associated with an altered cell dependent kinase activity is commensurate in scope with the disclosure of the present application. Moreover, the plain language of Claim 1

recites “cell proliferative disorders associated with an altered cell dependent kinase activity” and does not specify whether “HIV and Alzheimer’s disease” is included in the claimed disorder. Thus, applicants believe the Examiner’s allegation that Claim 1 includes HIV and Alzheimer’s disease is not justified.

The hallmark of cancer cells is the uncontrolled and dysregulated proliferation. It is generally recognized in the biomedical field that CDKs are rate-limiting enzymes in cell cycle progression and thereby direct inhibition of cdk/cyclin kinase activity can restrict the unregulated tumor cell proliferation.

With respect to the inhibition assays of cdk/cyclin, the present invention provides detailed experimental protocols and further recites that the compounds of formula (I) are active as cdk/cyclin inhibitors as they gave positive results when tested according to the procedure described therein (lines 9-10, page 23) and all compounds showing inhibition more than 50% were further analyzed in order to study and define the kinetic-profile of inhibitor through K_i calculation (lines 3-4, page 24). The specification also delineates pharmacological protocols as to the dosage, host, and mode of administration for using compounds of formula (I) in the treatment of cell proliferative disorders (pages 23-27).

It is known that the level of skill and the state of art in the pharmaceutical industry are very high. Particularly, various compounds are routinely tested through biological assays in pharmaceutical research. In view of such detailed description and the high level of the skill in the art, applicants submit that one skilled in the art would be able to practice the full scope of the claimed method without any undue experimentation.

Therefore, applicants respectfully submit that the present application satisfies the enablement requirement under 35 U.S.C. §112, first paragraph.

The rejections under 35 U.S.C. §112, first paragraph, have been obviated,
therefore reconsideration and withdrawal thereof is respectfully requested.

Thus, in view of the foregoing amendments and remarks, the application is in
condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Peter I. Bernstein', with a long horizontal flourish extending to the right.

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